

DOCKET NO.: CHIR-0212

PATENT**Remarks**

Claims 2-4, 7-10, 13-14, and 17 were pending. All pending claims were rejected in the Office Action. Claim 2 has been canceled herein without prejudice. The Applicant respectfully requests that the Examiner reconsider and withdraw the rejections in view of the foregoing amendments and arguments that follow.

Preliminarily, Applicant gratefully acknowledges the withdrawal of the previous grounds of rejections and objection.

The disclosure was objected to because of an informality. Specifically, the Examiner noted that the page numbers in the table of contents on pages 12-13 should be deleted because the pagination would not be retained in the printed patent. Correction was requested. Applicant has deleted the table of contents.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 2-4, 7-10, and 17 were rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner alleged that there was not sufficient description of the functionally equivalent variants and fragments. Applicant disagrees, but in order to advance prosecution, Applicant has cancelled claim 2 and reserves the right to pursue the subject matter thereof in a later filed case. Applicant respectfully traverses this rejection as applied to the remaining claims.

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As stated in the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1 'Written Description' Requirement,":

Possession may be shown by actual reduction to practice, by a clear depiction of the invention in detailed drawings which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention, or by a written description of the invention describing sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention.

In accordance with these standards, Applicant has indeed, provided a sufficient written description of the claimed invention. Although, as the Examiner observed, a sequence is not provided for the 24kd protein which specifically binds to the E2 protein of hepatitis C virus, one is not necessary for Applicant to have been in possession of variants and fragments of the protein. As disclosed and claimed, the 24 kd protein is obtained from membrane preparations of cells that bind the E2 protein of hepatitis C virus. As acknowledged by the Examiner, variants are defined as resulting from a chemical modification of the 24 kd protein (see page 3, lines 34-36, of the application as filed). One does not need a sequence to prepare variants by chemical modification, nor to be in possession of the same. Further, one does not need a sequence to prepare fragments of the protein, nor to be in possession of the same. For example, see "The Chemical Modification of Proteins by Group-Specific and Site-Specific Reagents," pp. 2-103, *The Proteins*, vol. II, Third Edition, Hans Neurath and Robert L. Hill, eds., Academic Press, N.Y., 1976. Modifications, including cleavage, are discussed. Applicant will forward a copy of the reference if the Examiner

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request. Applicant respectfully requests that this rejection be withdrawn.

Claims 2-4, 7-10, and 17 were rejected under 35 U.S.C. §112, first paragraph as allegedly not being enabled. The Examiner alleged that the production of functionally equivalent variants and fragments is not enabled by Applicant's specification. Applicant disagrees, but in order to advance prosecution, Applicant has cancelled claim 2 and reserves the right to pursue the subject matter thereof in a later filed case. Applicant respectfully traverses this rejection as applied to the remaining claims.

The enablement requirement of §112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (the legal standard for enablement under §112 is whether one skilled in the art would be able to practice the invention without undue experimentation). Indeed, a patent need not teach, and preferably omits, what is well known in the art. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984).

The Examiner cited, *inter alia*, *Ex parte Forman*, in support. The Examiner analyzed several of the factors set forth in *Ex parte Forman*, including predictability. Regarding predictability, the Examiner cited several references to support the proposition that a single amino acid change can drastically affect function of a protein. Applicant respectfully submits that the Examiner is misconstruing the predictability factor. The Examiner seems to be saying that Applicant needs to be able to predict which changes will give functionally equivalent variants and fragments. Such predictability is not required, however. The predictability recited by the case

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law is the predictability or lack thereof *in the art*. *In re Wands, supra*. The correct predictability analysis regards whether or not one would be able to "produce" functionally equivalent variants or fragments without undue experimentation, nor whether or not one would be able to "predict" *a priori* which changes will result in functionally equivalent variants. When the correct analysis is applied, it is clear that Applicant's claimed invention is enabled in combination with that which was well known in the art of protein chemistry. (See, *The Proteins*, above.) Applicant respectfully requests withdrawal of this rejection.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 2-4, 7-10, and 17 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite in view of the recitation "functionally equivalent variant or fragment thereof." Claim 2 has been canceled. Applicant respectfully traverses this rejection as applied to the remaining claims.

Again, the Examiner is focusing upon the absence of a sequence, alleging that without the same "the metes and bounds of [] amino acid insertions, deletions, and replacements cannot be determined and the claims are indefinite." (See Office Action at page 8.) As discussed above, however, discussion incorporated herein, one does not need to know the sequence of a protein to chemically modify that protein. Regardless, Applicant is claiming "all" functionally equivalent variants or fragments. Those skilled in the art, upon reading the claims in light of the specification, are apprised of the scope of the invention. See *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 USPQ 634 (Fed. Cir. 1985).

Objections

The Examiner objected to claim 2 as being in improper dependent format for filing to further limit the subject matter of a previous claim. Applicant has canceled claim 2. This objection has been rendered moot.

For the foregoing reasons, Applicant requests that claims 3-4, 7-10, and 17 be allowed at this time. A notice of allowance is earnestly solicited. If the Examiner thinks a telephonic

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discussion would be helpful, she is asked to contact the undersigned at 215-564-8352. Attached hereto is a marked-up version of the changes made to the claims by the current Response and Amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

Delete the section beginning on page 12, line 4, through page 13, line 2.

In the claims:

Claim 2 has been canceled.